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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,494	06/05/2001	Tseng-hui Timothy Chen	COUL-012/01US	7143

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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,494	CHEN ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 8-28* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,8-24 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed February 24, 2004. Amendments were made to the claims. Specifically, claims 1-3, 7 and 29 were cancelled.

Claims 4-6 and 8-28 are pending in the instant application. Claims 25-27 are withdrawn from consideration as being drawn to a non-elected invention. Claims 4-6, 8-24 and 28 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 29, 2003, that is not addressed in this action has been withdrawn.

Information Disclosure Statement

The information disclosure statements filed August 21, 2002 and September 20, 2002 have been considered, and a signed an initialed copy of each is attached to this Office Action. It is noted that the previous Office Action indicated that only the August 21, 2002 IDS was considered; however, the signed and initialed copy was not present in the file at the time of this Office Action. As a result, and to ensure Applicant properly receives a copy of the signed and initialed August 21, 2002 IDS, a signed and initialed copy is being re-sent.

Specification

The abstract of the disclosure is objected to because of the use of the term "novel." Because it is presumed that any patent application that issues is a new invention, the use of the term "novel" is considered improper. It would be remedial to remove the term "novel" from the Abstract. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4-6, 8-24 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Carter et al. (US 2002/0082411; see entire document; henceforth Carter (US)). It is noted that Carter (US) has a priority claim to US Application 60/191,274 (March 22, 2000) that has been recognized by the USPTO, evidenced by the presence of the claim to priority in PALM.

Carter (US) discloses an amino acid sequence where the first 24 amino acids are identical to those represented by SEQ ID NO: 7 of the instant application, and are encoded by a nucleotide sequence that is identical to SEQ ID NO: 3 of the instant application (see for example, SEQ ID NO: 91 of Carter (US)). The amino acid sequence (MGKKQTAVAFALALLALSMTPAYA) also fits the pattern M-X_n-(K/R)-(K/R)-J_m-P-X_p-Z-X-Z. This sequence represents a leader peptide sequence that is encoded by a nucleotide sequence that is operably linked in the 5'-to-3' direction to a nucleotide sequence encoding an MHC class II heterodimer (see the descriptor and sequence of SEQ ID NO: 91, page 87 of Carter (US)); it is important to note that on page 15, lines 31-35, Applicant considers the MHC proteins to be a part of the immunoglobulin superfamily. Carter (US) teaches this protein in the context of expression systems for the recombinant production of these proteins (see for example page 9, paragraph [0093]). More specifically, these proteins are encoded by nucleotide sequences that are operably linked to

promoter sequences (including bacterial promoters such as lac and beta-lactamase; see for example paragraph [0099]) that are operable in the host cells in which the proteins are to be produced (see for example paragraph [0095] and [0099]), as well as replication sequences (see for example paragraph [0096-0097]), transcriptional termination sequences (see for example paragraph [0098]) and ribosome binding sites (see for example paragraph [0102]). Carter (US) specifically states that more than one complex can be produced by placing multiple transcription cassettes in a single vector (i.e., using a fourth and fifth nucleotide sequence encoding a leader peptide-immunoglobulin fusion)(see for example paragraph [0105]), and that these peptides can be produced through their secretion through the cell membrane of the host cell (see for example paragraph [0106]). Finally, Carter (US) teaches linking two of these MHC class II heterodimer sequences together via a linker sequence as single chain MHC class II molecule (see for example paragraph [0042]), where the linker can be between 1 and 50 amino acids (or 3-150 nucleotides) in length (see for example paragraph [0046]). Thus, Carter (US) anticipates the instantly claimed invention.

Claims 4-6, 8-24 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Carter et al. (IDS reference F1; see entire document; henceforth Carter (WO)).

Carter (WO) discloses an amino acid sequence where the first 24 amino acids are identical to those represented by SEQ ID NO: 7 of the instant application, and are encoded by a nucleotide sequence that is identical to SEQ ID NO: 3 of the instant application (see for example, page 120-121 of Carter (WO), sequence 17 (pCRC187)). The first 24 amino acids of this sequence (MGKKQTAVAFALALLALSMTPAYA) also fit the pattern M-X_n-(K/R)-(K/R)-J_m-P-X_p-Z-X-Z. This sequence represents a leader peptide sequence that is encoded by a nucleotide

sequence that is operably linked in the 5'-to-3' direction to a nucleotide sequence encoding an MHC class II heterodimer; it is important to note that on page 15, lines 31-35, Applicant considers the MHC proteins to be a part of the immunoglobulin superfamily. Carter (WO) teaches this protein in the context of expression systems for the recombinant production of these proteins (see for example page 24, lines 23-27). More specifically, these proteins are encoded by nucleotide sequences that are operably linked to promoter sequences (including bacterial promoters such as lac and beta-lactamase) that are operable in the host cells in which the proteins are to be produced (see for example page 25, line 25 to page 26, line 19), as well as replication sequences, transcriptional termination sequences (see for example paragraph [0098]) and ribosome binding sites (see for example page 26, line 1-30). Carter (WO) specifically states that more than one complex can be produced by placing multiple transcription cassettes in a single vector (i.e., using a fourth and fifth nucleotide sequence encoding a leader peptide-immunoglobulin fusion)(see for example page 27, line 24-25), and that these peptides can be produced through their secretion through the cell membrane of the host cell (see for example page 27, line 7 to page 28, line 8). Finally, Carter (WO) teaches linking two of these MHC class II heterodimer sequences together via a linker sequence as single chain MHC class II molecule (see for example page 11, lines 11-15), where the linker can be between 1 and 50 amino acids (or 3-150 nucleotides) in length (see for example page 12, lines 13-14). Thus, Carter (WO) anticipates the instantly claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER